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November 23, 2020

Mr. Demson Fuller, PM Team 32
Regulatory Management Branch I
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

SUBJECT: Submission for an Amendment for Salt Cartridge for Giselle®
EPA Registration Number 91386-1

Dear Mr. Fuller:

On behalf of our client Industrie De Nora S.p.A. (De Nora; Via Bistolfi, 35, 20134 Milan, Italy; EPA Company Number 91386), Exponent is submitting the enclosed amendment for the registered product Salt Cartridge for Giselle® (EPA Registration Number 91386-1) containing sodium chloride. In support of this amendment submission please find enclosed the following:

- Transmittal Document (this letter);
- Application for Registration (EPA Form 8570-1);
- Certification with Respect to Citation of Data (EPA Form 8570-34);
- Data Matrix – Public and Private Versions (EPA Form 8570-35);
- Amended Product Label (with changes highlighted);
- Copy of most recent EPA Stamped Approved label;
- 5-batch analysis report (MRID 51369901);
- Emerging Viral Pathogens Terms of Registration Letter;
- Letter of Authorization for Exponent; and
- EPA Pesticide Registration Improvement Act Payment Confirmation Receipt, PRIA Category A570; Pay.gov Tracking ID 26QB86IT, Agency Tracking ID 76046177685.

Please note that the information in this cover letter and submission is considered ***Confidential Business Information*** and must not be disclosed to any party outside of EPA.

As discussed with OPP, De Nora seeks to amend their existing sodium chloride registration to include salt provided in bulk form for use in conjunction with De Nora's Clor-Tec SD® machine. The Clor-Tec SD machine converts the registered precursor chemical to produce a ready-to-use sodium hypochlorite solution for use as a disinfectant (0.6% concentration) and for dilution to a sanitizer at 0.1% and 0.05% concentrations.

The Clor-Tec SD uses the same technology and substantially similar process as the Giselle[®] machine. The product label has been amended to include the bulk salt for use in the Clor-Tec SD machine and to add the Clor-Tec SD machine to the labeling for the 0.6% sodium hypochlorite disinfecting solution and 0.1% and 0.05% sodium hypochlorite sanitizing solutions. The bulk salt for use in the Clor-Tec SD machine consists of commodity, pharmaceutical-grade sodium chloride.

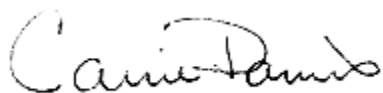
As discussed with the Agency, this amendment provides for the on-site production of larger volumes of sodium hypochlorite, via the Clor-Tec SD machine, which uses the same technology as the Giselle. The 5-batch analysis demonstrates that the active ingredient content of the material produced by the Clor-Tec SD machine meets the labeled concentration of 0.6%. The product analysis was conducted on sodium hypochlorite produced by five different Clor-Tec SD machines, each at three different times following start-up (10 minutes, 90 minutes, and 180 minutes), in order to demonstrate the reliability and consistency of the equipment. Because the Clor-Tec SD produces at least 0.6% sodium hypochlorite, the existing efficacy data will support the sodium hypochlorite produced by the Clor-Tec SD.

Additionally, the product label has been amended to add Emerging Viral Pathogens language for the 0.6% Sodium Hypochlorite Solution. The Emerging Viral Pathogens request letter is included in this submission package and details the viral data requirements supporting this request.

De Nora expects OPP will place the registration application into Pesticide Registration Improvement Extension Act category A570. A receipt for the fee payment also is included in this submission.

If there are any questions or comments concerning this registration amendment application, please contact Carrie Daniels via telephone at (703) 507-1963 or via email at cdaniels@exponent.com. A Letter of Authorization for OPP to speak with Exponent is included with this submission.

Sincerely,



Carrie Daniels
Authorized Representative for
Industrie De Nora S.p.A.

cc: Shannon Owings, Exponent, Inc.
Brent Shelley, Industrie De Nora S.p.A.

Enclosures